REMARKS

Rejection under 35 U.S.C. § 102

Claims 18-26 and 49-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Tucker et al. (4,193,397).

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

Claim 18 and Dependents

Applicant has amended claim 18. The amendment is supported by the original application. No new matter has been entered.

Claim 18 recites:

> manually applying pressure to a working fluid contained in an actuator associated with an implantable pharmaceutical fluid delivery device, wherein the implantable pharmaceutical fluid delivery device comprises a first fluid reservoir and a second fluid reservoir, thereby causing a flow of the working fluid into the first fluid reservoir;
>
> delivering to the treatment area a first dosage of pharmaceutical fluid from the second fluid reservoir by transferring pressure from the working fluid in the first reservoir to the pharmaceutical fluid in the second reservoir, wherein the working fluid and the pharmaceutical fluid are different fluids; and
>
> delivering to a treatment area a basal flow dosage of the pharmaceutical fluid from a constant flow pump as the first dosage is delivered, the constant flow pump associated with the implantable pharmaceutical fluid delivery device

Tucker discloses an infusion pump device that comprises two reservoirs to hold infusate. One reservoir is intended to function as a "basal" reservoir (see reservoir 12 in FIG. 5) and the other reservoir is intended to function as a "bolus" reservoir (see reservoir 38 in FIG. 5). By providing such reservoirs, a patient using the infusion pump of Tucker receives a

constant flow of infusate corresponding from the basal reservoir and can, at the patient's discretion, receive a bolus of infusate.

However, the structure that Tucker employs to provide such basal and bolus infusion differs from the structure specifically claimed in claim 18 and, hence, the method of claim 18 differs from the method of operation of the infusion device of Tucker.

Specifically, in claim 18, "working fluid" is stored in an actuator of the implantable pharmaceutical fluid delivery device. Upon application of manual pressure, working fluid is driven from the actuator into a first fluid reservoir. Thereafter, pressure is transferred from the working fluid in the first reservoir to pharmaceutical fluid in the second reservoir to deliver the pharmaceutical fluid from the second reservoir to the treatment area.

In contrast, the reservoirs of the infusion device of Tucker function independently. Specifically, reservoirs 12 and 38 are defined by independent bellows. The infusate for each reservoir is contained within the bellows and two-phase gas is contained immediately outside of each bellows to drive the infusate from the bellows. *See* col. 5, lines 52-57 and col. 6, lines 14-16. There is no "working fluid" as recited in claim 18 that transfers pressure from the one reservoir to another in the infusion device of Tucker.

Accordingly, claim 18 is not anticipated by Tucker. Claims 19-26 depend from claim 18 and, likewise, are not anticipated by Tucker.

Claim 49 and Dependents

Applicant has amended claim 49 to include the limitation previously recited in claim 50 (which is now cancelled).

Claim 49 recites:

> driving infusate from the main reservoir through a flow restrictor and out through a discharge port of the implantable infusion drug pump at a substantially constant basal infusion rate;
>
> providing a temporary bolus infusion rate in response to patient manipulation of an actuator of the implantable infusion drug pump, wherein the bolus infusion rate is provided simultaneously to the basal infusion rate, wherein the providing a temporary bolus infusion rate comprises: (i) drawing infusate from the main reservoir into a secondary reservoir using the actuator; and (ii) controlling a discharge rate from the secondary reservoir to the discharge port using a flow restrictor;...

wherein the implantable infusion drug pump comprises at least one one-way valve that enables the secondary reservoir to be filled without being subjected to a flow rate limitation of a flow restrictor of the implantable drug infusion pump.

Applicant notes that the Office Action merely states that Tucker discloses the "one-way valve" as recited in claim 49. However, the Office Action does not cite to a portion of Tucker to support the position or give a reference numeral corresponding to such a "one-way valve" in Tucker. Furthermore, Applicant is unable to identify such a "one-way valve" in Tucker.

Applicant respectfully submits that Tucker does not disclose this limitation and, hence, does not anticipate claim 49. Claims 51-54 depend from claim 49 are also not anticipated by Tucker.

In the next Office Action (to the extent that the Examiner maintains the position that Tucker discloses this limitation), Applicant respectfully requests the Examiner to identify the disclosure in Tucker describing such a valve and, preferably, cite the reference numeral used by Tucker.

Conclusion

Applicant respectfully submits that the application is in condition for allowance and requests the Examiner to pass the application to issue. Applicant believes no fee is due with this response. However, if a fee is due, please charge Deposit Account No. 50-3906 from which the undersigned is authorized to draw.

Applicant does not believe that an extension of time is necessary. However, if any extension of time is necessary, Applicant hereby petitions for such extension of time and authorizes the Office to charge Deposit Account No. 50-3906 from which the undersigned is authorized to draw for the appropriate extension of time fee.

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Respectfully submitted,

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